SURGICAL SERVICES
STANDARD ADVISORY COMMITTEE (SSSAC) MEETING

Tuesday, September 20, 2005

Michigan Library and Historical Center
702 West Kalamazoo Street
Lake Ontario Room
Lansing, MI 48915

APPROVED MINUTES

I. Call to Order.

Chairperson Miller called the meeting to order at 9:03 a.m.

a. Members Present and Organizations Represented:

Cheryl Miller, Trinity Health (Chairperson)
Eric Barnaby, Foote Health System (Alternate)
Evelyn Bochenek, RN, MSN, Sparrow Hospital
Charles Dobis, Michigan Ambulatory Surgery Association
John Fox, MD, Priority Health (left at 3:30pm)
Linda Fox, RN, Spectrum Health (left at 3:45pm)
Julie Greene, Michigan Medical Group Management Assoc. (arrived at table at 2:10 p.m.)
Toshiki Masaki, Michigan Manufacturers Association (left at 3:48 p.m.)
Rand O'Leary, Borgess Medical Center
Todd Regis, Michigan State AFL-CIO (arrived 1:15pm)
Krishna Sawhney, MD, Henry Ford Health System
Debra Stephenson, BSN-RN, MBA, CNOR, McLaren Health Care (arrived at 9:25 a.m.)
Walter Whitehouse, Jr., MD, The Saint Joseph Mercy Health System
Robert Wolford, Michigan Medical Group Management Assoc. (left at 2:10 p.m.)
George Yoo, MD, Barbara Ann Karmanos Cancer Institute

b. Members Absent and Organizations Represented:

Lowell Bursch, MD, Spectrum Health
Kim Meeker, RN, BSN, MBA, Foote Health System

c. Staff Present:

Lakshmi Amarnath
Tom Freebury (arrived at 9:41 a.m.)
Larry Horvath (arrived at 9:41 a.m.)
John Hubinger
Andrea Moore (left at 11:00 a.m.)
Stan Nash
Brenda Rogers
Gaye Tuttle
Matt Weaver

d. General Public in Attendance:

There were approximately 32 people in attendance.

II. Review of Agenda and Distributed Materials.

Chairperson Miller reviewed the agenda and distributed materials. Motion by Dr. Fox, seconded by Dr. Sawhney, to accept the Agenda as presented. Motion Carried.

III. Conflicts of Interests.

No conflicts were noted.

IV. Review of Minutes – August 17, 2005.

Chairperson Miller requested that the minutes reflect in that in Item V, SAC Action, modify to read "Option 1 carried with 10 votes, option 2 received 1 vote and option 3 received 3 votes, out of 14 total votes."

Dr. Fox requested that in Item VII, Rural Considerations, that the motion be corrected to show that "4 or fewer ORs would be potentially eligible."

Motion by Dr. Whitehouse, seconded by Ms. Bochenek, to accept the Minutes as adjusted. Motion Carried.

V. Review of CON Commission Action on September 13th.

Chairperson Miller reported that the Commission took action on proposed language (Attachment A), which was drafted and before the Commission at its September 13, 2005 meeting. The language will go to Public Hearing and return the Commission for Final Action at the December meeting. Discussion followed. The Committee asked the Department for additional data on the current number of operating rooms and the percentage of increase in recent years.

Break from 9:15 a.m. to 9:25 a.m.

Public Participation in Discussion:
Mr. Larry Horwitz, Economic Alliance of Michigan

VI. Surgical Volume Informal Workgroup – Report and Recommendation.

Mr. Robert Meeker provided the Committee with a verbal presentation and a written report (Attachment B) of the Workgroup's recommendation. Discussion followed.

Break from 10:40 a.m. to 10:50 a.m.

Discussion followed.

Lunch break from 12:18 p.m. to 1:00 p.m.

Motion by Dr. Whitehouse, seconded by Dr. Fox, to accept the recommendation for dedicated cystoscopy and endoscopy rooms, as presented. Motion carried

Motion by Dr. Whitehouse, seconded by Dr. Fox, to accept the recommendation for exemptions for special purpose Ors, as presented. Motion carried.

Motion by Dr. Sawhney, seconded by Dr. Whitehouse, to accept the recommendation related to the rural adjustments for facilities with 4 or less ORs, as presented. Motion Carried.

Motion by Mr. Dobis, seconded by Dr. Sawhney, to accept the minimum volume requirements as presented and to remove "renovate" from the maintenance volume requirement and to include "relocate" in the maintenance volume requirement.

Motion by Dr. Yoo, seconded by Dr. Fox to amend the previous Motion made by Mr. Dobis/Dr. Sawhney, by adding that the expansion volume requirements be rounded, i.e. 1,625 hours becomes 1,600 hours, 1,219 hours becomes 1,200 hours, and 1,128 cases becomes 1,200 cases. Motion Failed (2 – For and 12 - Against).

Motion by Mr. Masaki, seconded by Mr. Regis to amend the previous Motion made by Mr. Dobis/Dr. Sawhney, by modifying the utilization percent to 70% for inpatient and 75% for outpatient. Motion Failed (5 – For and 9 – Against).

Discussion followed.

Original Motion by Mr. Dobis/Dr. Sawhney Carried (8 – For and 6 – Against).

Motion by Dr. Fox, seconded Dr. Sawhney to accept the "blended method" as presented from the workgroup. Motion Carried (11 – For and 0 – Against).

Public Participation in Discussion:

Larry Horwitz, Economic Alliance of Michigan
Bob Meeker, Spectrum Health System
Mark Mailloux, University of Michigan Health System
Amy Barkholtz, Michigan Hospital Association
Julie Green, Grand Valley Surgical Center

VII. Separate Licensure of Facilities with Common Ownership.

Chairperson Miller reported that Foote Health System is withdrawing its request for consideration on this issue.

VIII. Review of Draft Language.

The Department will be revising the draft language to reflect today's action of the Committee. Chairperson Miller, Dr. Fox, Ms. Bochenek, Ms. Stephenson and Dr. Sawhney will work with Ms. Rogers to review the draft language prior to the next meeting.

IX. Response to the Presentation of Dr. Kahn.

Ms. Greene provided written (Attachment C) and oral testimony in response to the presentation of Dr. Kahn.

X. Agenda Planning.

- Draft Language
- Final recommendation to the Commission

XI. Future Meetings.

Wednesday, October 12, 2005
Thursday, October 20, 2005

XII. Public Comment.

None

Mr. Nash distributed draft 2004 Hospital & FSOF survey data (Attachment D). Discussion followed.

XIII. Adjournment.

Motion by Mr. O'Leary, seconded by Ms. Greene, to adjourn the meeting at 3:50p.m. Motion Carried.

ATTACHMENT A

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW STANDARDS FOR SURGICAL SERVICES

(BY AUTHORITY CONFERRED ON THE CERTIFICATE OF NEED COMMISSION BY SECTION 22215 OF ACT NO. 368 OF THE PUBLIC ACTS OF 1978, AS AMENDED, AND SECTIONS 7 AND 8 OF ACT NO. 306 OF THE PUBLIC ACTS OF 1969, AS AMENDED, BEING SECTIONS 333.22215, 24.207, AND 24.208 OF THE MICHIGAN COMPILED LAWS.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.

(2) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgical center, or a hospital licensed under Part 215 of the Code performing inpatient or outpatient surgical services are covered clinical services for purposes of Part 222 of the Code.

(3) A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

(4) The Department shall use sections 3, 4, 5, 6, 7, 8, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) The Department shall use Section 9, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(6)(a) These standards shall apply to the review of all Certificate of Need applications for surgical services for which the Director of the Department of Community Health has not made a final decision under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws, as of the effective date of these standards.

(b) In the case of an application which has been deemed submitted, but which has not received a final decision by the Director on the effective date of these standards, an applicant may request, and the Department shall grant, an extension of up to 60 days to the Director's decision date established under Section 22231(6), being Section 333.22231(6) of the Michigan Compiled Laws. This period shall be used for the submission and review of any information which may be necessary to show compliance with these standards. The Department shall consider this information before a final decision is made.

(c) If a final decision reverses a proposed decision approving the project, the administrative hearing provisions of Section 22231(8), being Section 333.22231(8) of the Michigan Compiled Laws, shall apply. If the proposed decision was a denial and an administrative hearing has been held, the Director shall permit a rehearing or continuation of the hearing in order to consider information submitted under this subsection, and shall consider the results of that hearing before a final decision is made.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

(b) "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

(c) "Burn care," for purposes of these standards, means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of

Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

(f) "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

(g) "Department" means the Michigan Department of Community Health.

(h) “Emergency Room,” for purposes of Section 6(2)(b) of these standards only, means a designated area in a licensed hospital and recognized by the Department of Consumer and Industry Services as having met the staffing and equipment requirements for the treatment of emergency patients.

(i) "Endoscopy" means visual inspection of any cavity of the body by means of an endoscope.

(j) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic procedures are performed.

(k) "Existing surgical service" means a surgical facility that, on the date an application is submitted to the Department, is licensed as part of a licensed hospital site or a freestanding surgical outpatient facility, or that is certified as an ambulatory surgical center.

(l) "Expand a surgical service" means the addition of one or more operating rooms at an existing surgical service.

(m) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208 of the Code. It does not include a surgical outpatient facility owned by, operated, and licensed as a part of a hospital at a licensed hospital site.

(n) "Hospital" means a health facility licensed under Part 215 of the Code.

(o) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to provide surgical services. It is the time from when a patient enters an operating room until that same patient leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any time a patient spends in pre- or post-operative areas including a recovery room.

(p) "Initiate a surgical service" means to begin operation of a surgical facility at a site that does not perform surgical services as of the date an application is submitted to the Department. The term does not include the relocation of a surgical service or one or more operating rooms meeting the requirements of Section 7.

(q) "Licensed hospital site" means either:

(i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(r) "Offer" means to perform surgical services.

(s) "Operating room" or "OR," for purposes of these standards, means a room in a surgical facility constructed and equipped to perform surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used exclusively for endoscopy or cystoscopy cases.

(t) "Operating suite," for purposes of these standards, means an area in a surgical facility that is dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision of surgery.

(u) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to a hospital for an overnight stay is not anticipated as being medically necessary.

(v) "Relocate a surgical service or one or more operating rooms" means changing the geographic location of an existing surgical facility or one or more operating rooms to a different site within the relocation zone.

(w) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of the site at which an existing surgical service is located if an existing surgical service is located in a nonrural county, or a 20-mile radius if an existing surgical service is located in a rural county.

(x) "Renovate an existing surgical service or one or more operating rooms" means a project that:

(i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or ASC;

(ii) does not involve new construction;
(iii) does not involve a change in the physical location within the surgical facility at the same site; and
(iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

Renovation of an existing surgical service or one or more operating rooms may involve a change in the number of square feet allocated to an operating suite. The renovation of an existing surgical service or one or more operating rooms shall not be considered the initiation, expansion, replacement, relocation, or acquisition of a surgical service or one or more operating rooms.

(y) "Replace a surgical service or one or more operating rooms" means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. The term does not include the renovation of an existing surgical service or one or more operating rooms.

(z) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "Revised standards for defining metropolitan areas in the 1990's" by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United States Office of Management and Budget, 55 F.R. p. 12154 (March 30, 1990).

(aa) "Sterile corridor," for purposes of these standards, means an area of a surgical facility designated primarily for surgical cases and surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses, laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or "clean."

(bb) "Surgical case" means a single visit to an operating room during which one or more surgical procedures are performed.

(cc) "Surgical facility" means either:
(i) a licensed freestanding surgical outpatient facility;
(ii) a certified ambulatory surgical center; or
(iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

(dd) "Surgical service" means performing surgery in a surgical facility.

(ee) "Trauma care," for purposes of these standards, means surgical services provided to a trauma patient in a licensed hospital site that has been verified as meeting the standards of the American College of Surgeons for a Level I or II trauma center, or equivalent standards.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours of use; and evaluating compliance with minimum volume requirements

Sec. 3. (1) The Department shall use the number of operating rooms pursuant to subsection (2) and the number of surgical cases, or hours of use, as applicable, pursuant to subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set forth in the applicable sections of these standards.

(2) The number of operating rooms for each type of surgical facility shall be determined as follows:
(a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

(i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily for obstetrical services.

(ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

(iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter shall not be considered as an operating room.

(iv) An operating room that is or will be used exclusively to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 1 burn care and 1 trauma care operating room shall be excluded pursuant to this subdivision.

(v) An operating room that is or will be used, though not exclusively, to provide surgical services to patients requiring burn care or trauma care, as those terms are defined in these standards. No more than 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision.

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms in which endoscopy or cystoscopy cases are or will be performed.

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively for endoscopy or cystoscopy cases.

(3) The number of surgical cases, or hours of use, shall be determined as follows:

(a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms, including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(v), but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection (2)(a)(i), (ii), (iii), and (iv).

(b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection (2)(b).

(c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall be excluded.

Section 4. Requirements for approval for applicants proposing to initiate a surgical service

Sec. 4. (1) An applicant proposing to initiate a surgical service shall demonstrate that each proposed operating room shall perform an average of at least 1,200 surgical cases per year per operating room in the second 12 months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural county that does not offer surgical services as of the date an application is submitted to the Department.

(3) AN applicant shall demonstrate that it meets the requirements of Section 10(2) FOR THE NUMBER OF SURGICAL CASES PROJECTED UNDER SUBSECTION (1).

Section 5. Requirements for approval for surgical services proposing to expand an existing surgical service

Sec. 5. (1) An applicant proposing to add one or more operating rooms at an existing surgical service shall demonstrate each of the following:

(a) all existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,200 surgical cases or

(ii) in a hospital, 1,600 hours of use or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data is available to the Department.

(b) All operating rooms, existing and proposed, are projected to perform an average of at least:

(i) 1,200 surgical cases or

(ii) in a hospital, 1,600 hours of use or in an FSOF OR ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(2) Subsection (1) shall not apply if the proposed project involves adding a second operating room in a licensed hospital site located in a rural county that currently has only one operating room.

(3) AN applicant shall demonstrate that it meets the requirements of Section 10(2) FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (1).

SECTION 6. REQUIREMENTS FOR APPROVAL FOR FACILITIES PROPOSING TO REPLACE A SURGICAL SERVICE OR ONE OR MORE OPERATING ROOMS

Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating rooms at the same site shall demonstrate each of the following:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,200 surgical cases or

(ii) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data is available to the Department.

(b) All operating rooms, existing and proposed, are projected to perform an average of at least:

(i) 1,200 surgical cases or

(ii) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(2)(a) Subsection (1) shall not apply if the proposed project involves replacing one or more operating rooms at the same licensed hospital site, if the surgical facility is located in a rural county and has one or two operating rooms.

(b) Subsection (1) shall not apply if the proposed project involves replacing one or two operating rooms at the same licensed hospital site if the surgical facility is a hospital that:

(i) is located in a nonrural county;

(ii) has an emergency room at the same licensed hospital site as the operating rooms;

(iii) has exactly two operating rooms; and

(iv) has performed at least 1,200 surgical cases, or at least 1,600 hours of use, per year for the most recent 12-month period for which verifiable data is available to the Department.

Section 7. Requirements for approval for applicants proposing to relocate a surgical service or one or more operating rooms

Sec. 7. An applicant proposing to relocate a surgical service or one or more operating rooms shall demonstrate each of the following, as applicable:

(1) The proposed relocation will not result in an increase in the total number of operating rooms operated by an applicant at the existing and proposed sites unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The proposed new site is located within the relocation zone.

(3) All existing operating rooms in the surgical facility to be relocated have performed an average of at least:

(a) 1,200 surgical cases or

(b) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room for the most recent 12-month period for which verifiable data is available to the Department.

(4) All operating rooms, existing and proposed, are projected to perform an average of at least:

(a) 1,200 surgical cases or

(b) in a hospital, 1,600 hours of use, or in an FSOF or ASC, 1,800 hours of use per year per operating room in the second twelve months of operation, and annually thereafter.

(5) AN applicant shall demonstrate that it meets the requirements of Section 10(2) FOR THE NUMBER OF SURGICAL CASES, OR HOURS OF USE, PROJECTED UNDER SUBSECTION (4).

Section 8. Requirements for approval for applicants proposing to acquire an existing surgical service

Sec. 8. An applicant proposing to acquire an existing surgical service shall demonstrate each of the following, as applicable:

(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.

(2) The location of the surgical service does not change as a result of the acquisition unless an applicant can demonstrate compliance with the applicable requirements of Section 7.

(3) An applicant agrees and assures to comply with all applicable project delivery requirements.

(4) For the first application for proposed acquisition of an existing surgical service, for which a final decision has not been issued, on or after January 27, 1996, an existing surgical service to be acquired shall not be required to be in compliance with the volume requirements applicable to the seller/lessor on the date the acquisition occurs. The surgical service shall be operating at the applicable volume requirements in the second 12 months after the effective date of the acquisition, and annually thereafter.

(5) For any application for proposed acquisition of an existing surgical service except the first application, for which a final decision has not been issued, after the effective date of these standards, an applicant shall be required to document compliance with the volume requirements applicable to the existing surgical service on the date an application is submitted to the Department.

(6) Subsection (5) shall not apply if the proposed project involves the acquisition of both of the operating rooms of an existing surgical service of a hospital if the hospital from which the service being acquired is: (A) located in a nonrural county, (b) has an emergency room at the same licensed hospital site as the operating rooms, (c) has exactly two operating rooms, and (d) has performed at least 1,200 surgical cases or at least 1,600 hours of use per year for the most recent 12-month period for which verifiable data is available to the department. The operating rooms acquired under this subsection must remain part of a surgical service of a licensed hospital.

Section 9. Project delivery requirements -- terms of approval for all applicants

Sec. 9. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of Certificate of Need approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(c) Compliance with the following terms of approval, as applicable:

(i) The approved services and/or operating rooms shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) not deny surgical services to any individual based on ability to pay or source of payment;

(B) provide surgical services to any individual based on the clinical indications of need for the service.

(C) maintain information by payer and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) An applicant shall participate in a data collection network established and administered by the Department. The data may include, but is not limited to, hours of use of operating rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payer sources. An applicant shall provide the required data on a separate basis for each licensed or certified site, in a format established by the department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(iv) Within 10 days after initiation of the service, an applicant shall provide the Department with a notice stating the first date on which the approved service was initiated.

(d) Compliance with the following quality assurance standards, as applicable:

(i) Surgical facilities shall have established policies for the selection of patients and delineate procedures which may be performed in that particular facility.

(ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including cardiopulmonary resuscitation.

(iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of patients when necessary. All surgeons who perform surgery within the facility shall have evidence of admitting privileges or of written arrangements with other physicians for patient admissions at a local hospital. The surgical facility shall have an established procedure, including a transfer agreement, that provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the surgical facility to a hospital that is capable of providing the necessary inpatient services and is located within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an applicant shall have a transfer agreement with the nearest hospital having such capability.

(iv) An applicant shall have written policies and procedures regarding the administration of a surgical facility.

(v) An applicant shall have written position descriptions which include minimum education, licensing, or certification requirements for all personnel employed at the surgical facility.

(vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, or dentistry.

(vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including biologicals) services, either on-site or through contractual arrangements.

(viii) An applicant shall have written policies and procedures for advising patients of their rights.

(ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient records.

(x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

(xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel, and the public. Each facility shall incorporate a safety management program to maintain a physical environment free of hazards and to reduce the risk of human injury.

(e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an ambulatory surgical center.

(2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(3) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 10. Documentation of projections

Sec. 10. (1) An applicant required to project volumes of service under the applicable sections of these standards shall specify how the volume projections were developed AND SHALL INCLUDE ONLY THOSE SURGICAL CASES PERFORMED IN AN OR. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

(2) If a projected number of surgical cases, or hours of use, UNDER SUBSECTION (1) includes surgical cases, or hours of use, performed at ANOTHER existing surgical facility(s), an applicant shall demonstrate, with documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in compliance with the volume requirements applicable to that facility, and will be in compliance

with the volume requirements applicable to that facility subsequent to the initiation, expansion, or relocation of the surgical services proposed by an applicant. In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) The name of each physician that performed surgical cases to be transferred to the applicant surgical facility.

(b) The number of surgical cases each physician, identified in subdivision (a), performed during the most recent 12-month period for which verifiable data is available.

(c) The location(s) at which the surgical cases to be transferred were performed, including evidence that the existing location and the proposed location are within 20 miles of each other.

(d) A written commitment from each physician, identified in subdivision (a), that he or she will perform at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3 years subsequent to the initiation, expansion, or relocation of the surgical service proposed by an applicant.

(e) The number of surgical cases performed, at the existing surgical facility from which surgical cases will be transferred, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable annual survey data is available.

(3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of use in documenting compliance with the applicable sections of these standards, if an applicant provides documentation, satisfactory to the Department, from the surgical facility from which the hours of use are being transferred.

Section 11. Effect on prior Certificate of Need review standards; comparative reviews

Sec. 11. (1) These Certificate of Need review standards supercede and replace the Certificate of Need Review Standards for Surgical Facilities approved by the Certificate of Need Commission on December 12, 1995 and effective on January 27, 1996.

(2) Projects reviewed under these standards shall not be subject to comparative review.

ATTACHMENT B

Surgical Volume Work Group

Final Report
to the
Surgical Services
Standards Advisory Committee (SAC)

Of the CON Commission

September 20, 2005

Recommendations

A summary of the recommendations of the Surgical Volumes Work Group is as follows:

1) The need approach for surgical services should be modified to include the following:
   a) Separate determinations of need for inpatient and outpatient surgical services, regardless of setting; and
   b) Separate requirements for maintenance of current surgical capacity and for expansion of new surgical capacity.

      As a result, the volume requirements for surgical services should be as follows:

In order to maintain existing capacity or replace, or renovate existing operating rooms:

- Inpatient service –
  - **1,500** hours per operating room per year, or
  - **1,042** cases per operating room per year.
- Outpatient service –
  - **1,125** hours per operating room per year, or
  - **1,042** cases per operating room per year.

In order to expand existing capacity or initiate new service:

- Inpatient service –
  - **1,625** hours per operating room per year, or
  - **1,128** cases per operating room per year.
- Outpatient service –
  - **1,219** hours per operating room per year, or
  - **1,128** cases per operating room per year.

2) Hospital-based surgical services should be permitted to employ a 'blended method" of determining operating room need, whereby a hospital could employ the hours-based standard for inpatient surgical capacity and the cases-based standard for outpatient surgical capacity.

3) A separate need standard should be applied to rural surgical facilities, taking into account the unique difficulties of operating surgical services in rural areas.

      As a result, the volume requirements for rural surgical services should be as follows:

In order to maintain existing capacity or replace, or renovate existing operating rooms:

- **1,200** hours per operating room per year, or
- **839** cases per operating room per year.

In order to expand existing capacity or initiate new service:

- **1,300** hours per operating room per year, or
- **909** cases per operating room per year.

4) The special exemptions for hospitals with Burn Centers and Trauma Centers should be simplified, so that they receive a credit of .5 operating rooms, each, without any adjustment in their reported surgical volume. Hospitals with open-heart surgery programs should not receive similar exemptions.

5) The status of dedicated cystoscopy and endoscopy rooms should be formalized within the CON review process. Surgical facilities wishing to designate specific operating rooms as dedicated cystoscopy and endoscopy rooms should file non-substantive CON applications. Facilities wishing to designate dedicated cystoscopy and endoscopy rooms as general-purpose operating rooms should file regular, substantive CON applications for expansion of surgical capacity.

Surgical Volume Work Group

Final Report to the Surgical Services SAC

Introduction

At its meeting on August 17, 2005, the Surgical Services SAC established a second work group to investigate several issues related to CON volume requirements for surgical facilities. They are as follows:

1. Evaluation of the minimum volume requirements contained in the Surgical Services CON Review Standards;
2. Consideration of a "blended method" of demonstrating need for hospital-based surgical programs with combined volumes of inpatient and outpatient surgeries;
3. Definition of physically-distinct inpatient and outpatient surgical departments in the same hospital;
4. Consideration of Rural Issues;
5. Evaluation of the current exemption for trauma and burn centers and consideration of the need for a special exemption for dedicated open-heart surgery rooms; and
6. Determination of the status of dedicated cystoscopy and endoscopy rooms under the CON Standards.

The Work Group met three (3) times – August 22, 2005; August 29, 2005; and September 8, 2005. More than a dozen members participated in all three (3) meetings. They included managers of both hospital-based and free-standing surgical facilities, planners, consumer representatives, and MDCH staff. Members who attended one or more meetings of the group are listed in Attachment A. At no time was there a quorum of members of the SAC in attendance.

Recommendations of the Work Group related to these issues are as follows:

Minimum Volume Requirements

The Work Group reviewed the planning model employed by the 1995 Advisory Committee, as presented at the June 2, 2005 meeting of the Surgical Services SAC. The Group agreed that the 1995 model included the relevant variables in determining need for surgical facilities, as follows:

1. Annual days of operation (days/year)
2. Daily hours of operation (hours/day)
3. Utilization percentage, (utilization %)
4. Average length of case (case length)

The formulae for calculating volume requirements for surgical facilities are as follows:

Hours/OR/year = (days) x (hours/day) x (utilization %)

Cases/OR/year = (hours/OR/year) / (case length)

In a departure from the 1995 effort, the Work Group determined that there should be differential volume requirements to expand surgical capacity, as opposed to maintaining existing capacity. In other words, the project delivery requirements to maintain the existing complement of operating rooms should be less rigorous than the requirement to initiate a new surgical facility or to expand an existing one. This approach is consistent with other CON Review Standards which include higher thresholds for expansion than for replacement. The Work Group calculated different volume requirements by varying the utilization percentages in the planning model.

The Work Group focused much attention on the concept of "utilization percentage." The previous advisory committee called this factor "efficiency level," and considered it to account for unavoidable down time in a surgical facility due to scheduling problems, cancellations, and other delays. As used in the contemporary literature, and also by the Work Group, "utilization percentage" takes into account all of the preceding considerations, plus turn-around time (set-up and clean-up) between surgical cases. Professional literature reviewed found an average utilization of 63% for the best-performing quartile of hospital-based surgery departments surveyed. The Work Group recognized that utilization percentage, like occupancy percentage for hospital beds, is a critical factor in calculating need for licensed operating rooms.

In a further departure from the 1995 effort, the Work Group determined that there should be different volume requirements for inpatient surgical services and outpatient (regardless of setting) surgical services. As a result, hospitals would separately calculate their inpatient and outpatient need for operating rooms, and sum them to produce the facility need for surgical capacity.

The Work Group evaluated different values for each of the planning variables, separately for inpatient and outpatient surgical services. In addition to the work of the previous advisory group and materials distributed to the SAC, the Work Group drew information from supplemental literature related to management of surgical facilities (see reference list), from professional experience of individual Work Group members, and from data derived from the special survey of surgical facilities conducted by MDCH. After considerable discussion and review, the Work Group determined the most appropriate values to be as follows:

1. Annual days of operation — 250 days per year
2. Scheduled daily hours of operation — Inpatient – 10 hours; Outpatient – 7.5 hours
3. Utilization percentage — Maintenance – 60%; Expansion – 65%
4. Average length of case — Inpatient – 2.2 hours; Outpatient – 1.08 hour

The results of employing these factors are presented in the table in Attachment B.

The Work Group further considered these results. For inpatient services, where the use of surgical hours generally produces the most appropriate estimate of operating room need, the resulting minimum requirements measured by surgical cases, were determined to be unreasonably low. Therefore, the Work Group recommends that hospitals wishing to use cases as an indicator of need for their inpatient volume should use the same standard as applied to outpatient services. Therefore, the Work Group recommends that the minimum volume requirements per operating room per year should be as follows:

- Maintain existing capacity, replace, renovate

Measure per OR per yr	Inpatient	Outpatient	Current Requirements
Hours	1,500	1,125	1,600 hospital 1,800 FSOF
Cases	1,042	1,042	1,200

- Expand existing capacity, initiate new service

Measure per OR per yr	Inpatient	Outpatient	Current Requirements
Hours	1,625	1,219	1,600 hospital 1,800 FSOF
Cases	1,128	1,128	1,200

These thresholds were agreed to by a consensus of the Work Group members, with the representative of the Economic Alliance abstaining.

"Blended Method" for Hospital-Based Surgical Departments

The approach endorsed by the Work Group includes separate need determinations for inpatient and outpatient surgery, regardless of site. The original blended method proposed to the SAC would have allowed mixing measures (i.e., hours and cases) for hospital-based surgical departments. The Work Group recommends that, in addition to using either hours or cases to determine the need for operating rooms, hospitals should be allowed to combine the inpatient operating room need indicated using inpatient hours with the outpatient operating room need using outpatient cases to determine the total need for surgical capacity at the facility.

Physical Distinctness of Hospital-Based Inpatient and Outpatient Surgical Departments

Since the recommendations for revised volume requirements distinguish between need for inpatient and outpatient surgical capacity, the Work Group recommends that there is no need to define physically-distinct inpatient and outpatient surgical departments at a hospital for CON purposes.

Rural Issues

Representatives of rural hospitals made a compelling case to the SAC about the unique difficulties of operating surgical departments in rural hospitals. The Work Group reviewed the data from the MDCH special surgical survey related to rural facilities. The Group acknowledged the particular difficulties of rural hospitals in scheduling longer than eight (8) hours per day. They also determined that the difference between inpatient and outpatient cases at rural hospitals is less significant than at urban hospitals. Therefore, the Work Group determined that the most appropriate values in the need methodology for rural surgical services to be as follows:

1. Annual days of operation 250 days per year
2. Scheduled daily hours of operation 8 hours
3. Utilization percentage Maintenance – 60%; Expansion – 65%
4. Average length of case 1.43 hours

The results of employing these factors are presented in the table in Attachment C.

As a result, the work group recommends that the minimum volume requirements per operating room per year for rural surgical facilities should be as follows:

- Maintain existing capacity, replace, renovate,

Measure per OR per yr		Current Requirements
Hours	1,200	1,600 hospital 1,800 FSOF
Cases	839	1,200

- Expand existing capacity, initiate new service

Measure per OR per yr		Current Requirements
Hours	1,300	1,600 hospital 1,800 FSOF
Cases	909	1,200

These thresholds were agreed to by a consensus of the Work Group members, with the representative of the Economic Alliance abstaining.

Exemptions for Special Purpose Operating Rooms

The Work Group reviewed the rationale for exemptions for surgical rooms designated for burn patients and trauma patients. They determined that an exemption for these purposes continues to be justified, but that it should be simplified. Therefore, the Work Group recommends that qualified burn and trauma centers should receive a credit of .5 operating rooms, each, without any adjustment in their case/hours count.

They also considered the justification for a similar exemption for open-heart surgery programs. Because most open-heart procedures are scheduled, rather than emergent, and that there is no requirement to dedicate a specific room for heart surgery, the Group determined that no exemption is warranted for open-heart surgery.

Dedicated Cystoscopy and Endoscopy Rooms

The Work Group acknowledged that surgical facilities should be permitted to designate specific operating rooms on the sterile corridor as dedicated cystoscopy and/or endoscopy rooms. However, they determined that such designation should be formalized through the CON process. The Work Group recommends that any change in a hospital's licensed complement of operating rooms that changes the designation of a general-purpose operating room to a dedicated endoscopy and/or cystoscopy room should require non-substantive CON approval. Furthermore, any change in a hospital's licensed complement of operating rooms that changes the designation of a dedicated endoscopy and/or cystoscopy room to a general-purpose operating room should be considered an expansion of the surgical capacity of that facility and, hence, require substantive CON approval.

Summary

The Work Group developed recommendations on each of the tasks assigned to it. All issues received appropriate deliberation and final recommendations reflect reasonable compromise among the participants. A summary of the Work Group recommendations is as follows:

1) The need approach used by the 1995 Ad Hoc Advisory Committee was endorsed and updated. Two significant improvements were introduced:
   a) Separate determinations of need for inpatient and outpatient surgical services, regardless of setting; and
   b) Separate requirements for maintenance of current surgical capacity and for expansion of new surgical capacity.

   All planning assumptions used in the original approach were examined and updated. New CON requirements were developed based on review of best practices and professional literature related to management of surgical facilities; on the professional experience of individual Work Group members; and on consideration of data derived from the special survey of surgical facilities conducted by MDCH.

2) A 'blended method" of determining hospital-based operating room need was endorsed, whereby a hospital could employ the hours-based standard for inpatient surgical capacity and the cases-based standard for outpatient surgical capacity. Because the proposed new volume requirements take into account the differences between inpatient and outpatient surgical services, there is no need to define physically-distinct inpatient and outpatient surgical departments in a hospital.
3) A separate need standard was developed for rural surgical facilities taking into account the unique difficulties of operating a surgical service in a rural area.
4) The validity of special exemptions for hospitals with Burn Center and Trauma Center designations was reaffirmed, and the specifics of these exemptions were simplified. A similar exemption for open-heart surgery programs was rejected.
5) The status of dedicated cystoscopy and endoscopy rooms was clarified and the CON review process for those specialized operating rooms was specified.

Specific language reflecting these recommendations is under development and will be forwarded to the SAC as it is available.

These recommendations reflect decisions made at the Work Group meeting on September 8, 2005. This report was reviewed by Work Group participants and modified as a result of their comments prior to final submission to the SAC.

References

Association of PeriOperative Registered Nurses (AORN), *PeriOperative Management Resources: OR Renovation/Construction*; 2005; AORN, Denver, Co.

Fernsebner, Billie; *Competencies for Management of the Operating Room*, 2nd Edition; 2000; OR Manager, Inc, Sante Fe, NM.

Frye, Cathy (Ed.); *Perioperative Services: Administration, Resource Management, and Patient Care*; 2000; Aspen Publishers, Inc., New York, NY.

Lowery, Julie C. and Jennifer A. Davis; "Determination of Operating Room Requirements Using Simulation;" *Proceedings of 1999 Winter Simulation Conference*; Farrington et. al. (Eds.); 1999; 1568-72.

Stodd, Kay, Alex Ortiz and Inez Tenzer; "Operating Room Benchmarking: The Kaiser Permanente Experience;" *Permanente Journal*; Fall, 1998.

Tyler, Donald C., Caroline A. Pasquariello and Chun-Hung Chen; "Determining Optimum Operating Room Utilization;' *Anesth. Analg*; 2003; 96: 114-21.

ATTACHMENT A

ATTENDEES AT MEETINGS OF THE SURGICAL VOLUME WORK GROUP

Participant *	Organization
1. Amy Barkholz	MHA
2. * Evelyn Bochenek	Sparrow Health System
3. Cindy Collison	Grand Valley Surgical Center
4. Penny Crissman	Crittenton Hospital
5. Melissa Cupp	Weiner Associates
6. * Julie Greene	Grand Valley Surgical Center
7. Monica Harrison	Oakwood Healthcare System
8. Larry Horwitz	Economic Alliance
9. Barbara Jackson	Economic Alliance
10. Matt Jordan	Kheder Davis & Associates
11. Barbara Loventhal	Henry Ford Health System
12. Mark Mailloux	University of Michigan Medical Center
13. Robert Meeker	Spectrum Health
14. * Cheryl Miller	Trinity Health
15. Stan Nash	MDCH
16. Benjamin Reigle	Borgess Health System
17. * Carolyn Skaff	The Surgery Center
18. * Debra Stephenson	McLaren Health System
19. Matt Weaver	MDCH
20. Susan Wyman	St. Joseph Mercy Health

* SAC members or alternates

Meeting Dates: August 22, 29, and September 8, 2005

ATTACHMENT B

Calculation of OR Need for Urban Surgical Facilities Using Final Values for Planning Variables

	Inpatient		Outpatient	
	Maintain	Expand	Maintain	Expand
Days/yr.	250	250	250	250
Hours/day	10	10	7.5	7.5
Hours/year	2,500	2,500	1,875	1,875
Utilization percentage	60%	65%	60%	65%
Adj. Hours/year	1,500	1,625	1,125	1,219
Hours/case	2.2	2.2	1.08	1.08
Cases/year	682*	738*	1,042	1,128

* **Note**: After reviewing these results of applying the agreed values for all the planning variables, the Work Group determined that case volumes indicating the need for inpatient operating rooms should be the same as those for outpatient operating rooms. Hence, these numbers have been changed in the final recommendations.

ATTACHMENT C

Calculation of OR Need for Rural Surgical Facilities Using Final Values for Planning Variables

	Maintain	Expand
Days/yr.	250	250
Hours/day	8	8
Hours/year	2,000	2,500
Utilization percentage	60%	65%
Adj. Hours/year	1,200	1,300
Hours/case	1.43	1.43
Cases/year	839	909

ATTACHMENT C

SSSAC Testimony submitted and presented by Julie Greene, Tuesday, September 20, 2005

Good afternoon. My name is Julie Greene and I am the Executive Director of the Grand Valley Surgical Center in Grand Rapids, Michigan and the current President of the Michigan Ambulatory Surgical Association.

I felt the need to submit formal testimony today because I was very concerned about information regarding the role ASCs play in providing health care that has been submitted in prior testimony.

At a time when the citizens of Michigan, like all Americans, are more concerned than ever about access to affordable health care, I do not believe it is sound health policy to promote changes to the CON regulations that could prevent the development of ASCs. Indeed, from a health planning perspective, the most remarkable thing about the growth of ASCs over the last three decades has been their unique ability to provide high quality care and outstanding customer service while simultaneously reducing costs for the health care system. That combination is exceedingly rare nowadays. In fact, the most promising developments in health care services and technology almost invariably come with a significant price tag, as evidenced by the large growth in health care spending.

Advances in technology have contributed to the movement of procedures from the inpatient to the outpatient setting. Thirty years ago, virtually all surgery was performed in hospitals and patients typically spent several days in the hospital and several weeks out of work in recovery. Today, it is estimated that almost 80 percent of surgery in the United States is done on an outpatient basis.' This includes surgery in AS Cs, in hospital outpatient departments, and in physician offices. Some of these advances include faster acting anesthetics and less invasive surgical techniques, such as arthroscopy. Procedures that only a few years ago required major incisions and extended convalescence in a hospital are now routinely performed in an outpatient setting with minimal recovery time.

Rather than read previous testimony, I have provided written excerpts that initiated my response.

Excerpt from previous testimony:

I support CON as one of our strongest tools to deliver good care to Michigan at a time when demandfor care, cost escalation, and question about quality all threaten the continuation of the American health care system. Our CON program among other things should pro vide integration with other state programs and be designed,for example, to address costs, quality assurance and licensure issues.

In that regard, I am particularly concerned about the proliferation offree standing surgical outpatient facilities (FSOF's) and the ability of our economy, state, businesses and citizens to withstand another round of certain cost escalation. The 2004 AHA Survey noted that Pennsylvania's ambulatory surgery usage per 1000 was 32% higher than the U.S. average. Pennsylvania then had no CON. 48 new surgical centers opened there in 2003. That growth raises cost and quality concerns and demonstrates the pressure you will see for ambulatory surgical center expansion. END OF QUOTE

Unfortunately, previous testimony has tied the existence of free standing surgical outpatient facilities (FSOF's) to "certain cost escalation". It noted Pennsylvania as a statistical example. Even if Pennsylvania does have a 32% higher ambulatory surgery usage than the rest of the United States, it does not mean all of those surgeries took place in surgical centers. In fact, in

2004, only 11.85% of ambulatory surgeries in Pennsylvania were performed in FSOF's. That is up *1.55%* from the 2003 numbers.

The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of health care and increasing access for all citizens regardless of ability to pay. I will read some excerpts from the following news release distributed on July 13, 2005:

Harrisburg, PA - July 13, 2005 - In the first report of its kind, Pennsylvania hospitals reported 11,668 confirmed hospital-acquired infections in 2004, according to a Research Brief titled *Hospital-acquired Infections in Pennsylvania* released today by the Pennsylvania Health Care Cost Containment Council (PHC4). The hospital admissions in which these infections occurred were associated with 1,793 deaths, and an estimated 205,000 extra hospital days and $2 billion in additionafi hospital charges. These numbers are out of a total of *1.5* million discharges from 173 general acute care hospitals.

"This seminal report demonstrates without question that the cost and quality implications of potentially preventable hospital infections are astounding," stated Marc P. Volavka, Executive Director of PHC4. "This first snapshot of statewide numbers should be a wake up call for all parties involved in the delivery and payment of hospital care.

29 hospitals (17%), which account for 25% of ALL statewide admissions, reported more than half *(50.6%)* of the 11,668 hospital-acquired infections. Several large hospitals submitted invalid infection data for the majority of their discharges. Sixteen hospitals, including several large hospitals, reported no infections at all.

One of PI-1C4's major interests is the discrepancy between the number of hospital-acquired infections reported by hospitals (11,668) and the 115,631 infections billed to purchasers, private insurers and government programs like Medicare and the state's Medical Assistance program. PHC4 screened the 2004 billing data for diagnoses that may possibly indicate the presence of a hospital-acquired infection. While it is reasonable to assume that not all these infections are acquired in the hospital, these billed infections suggest the possibility of more hospital-acquired infections than those confirmed by hospitals and reported to PHC4.

PHC4, also for the first time, was able to look at actual payment data for these occurrences. Previously, all cost assumptions were based on hospital charges, which are not what hospitals are actually paid in heavily discounted arrangements with insurance companies. The newly submitted payment data from third party payors shows that in 2003, the average payment for the treatment of a patient with an infection was more than $29,000, compared to an average payment of $8,300 for a patient without an infection.

Assuming payments remained static between 2003 and 2004, PHC4 estimates that third party insurance payments (distinct from hospital charges) for just the 11,668 reported infections were nearly $350 million annually. "Quality improvement efforts must be redoubled, and hospital Boards and CEOs, along with those paying the bills, must insure that infection control departments and their dedicated staff get the support and resources they need to reduce infections to the most minimally acceptable level. The quality case is imperative, the business case is compelling," stated Mr. Volavka. END OF QUOTE

I would say that the citizens of Pennsylvania are probably greatly benefiting from the growth of ambulatory surgery centers due to typically lower infection rates than hospitals. Nearly 90% of ASCs report having less than 3 infections per 1,000 patient encounters. Almost two-thirds

reported having zero infections.[2] Certainly a significant variable related to this statistic is the absence of ill and infectious patients that are found in hospital facilities.

In Pennsylvania, between 2003 and 2004 total ambulatory surgery records increased from 1,966,390 to 2,096,231 or 1590 per 10,000 residents to 1690 per 10,000 residents. This constitutes a 6.6% increase. Furthermore, the increase from 2002 to 2003 was a *3.45%* increase, another "not so alarming" figure according to the Pennsylvania Health Care Cost Containment Council. If Pennsylvania has a much higher than US average of ambulatory surgery usage, it is not due to free standing outpatient facility growth.

From a cost perspective, the growth ratio in hospital ambulatory facility charges compared to record growth is much higher among the Pennsylvania hospitals than it is among the Pennsylvania free-standing facilities. It is interesting to note that the hospital ambulatory surgery records increased by *2.58%* from 2003 to 2004 and the hospital ambulatory surgery charges increased 12.93%. At the same time the FSOF records increased 23% from 2003 to 2004, while the FSOF charges only increased 11.85%. These facts would not provide evidence that FSOFs are the reason for cost escalation in Pennsylvania.

Excerpt from previous testimony:
However, when the potentialfor total costs associated with procedures explosion threaten to outstrip any saving from the reduction in price for an individual service, I become very concerned. When inappropriate procedure explosion occurs total medical expenditures rise and payors are economically damaged. In Pennsylvania between 2000 and 2003 outpatient surgical and diagnostic procedures grew from 9% to 20% of all procedures performed.
END OF QUOTE

Excerpt from previous testimony:

We live in an environment where Medicaid is paying hospitals well below their cost (about 70% of costs) for the provisions of services. This makes any sane business model catering to service Medicaid patients or private pay patients impossible for the freestanding surgicalfadiity. The obvious result, therefore, is that hospitals will be comp eting for their only paying customers with the ESOEs and left to eat the cost of their losing customers since the federal EMTALA laws require hospitals but NOT the freestanding surgery centers, to treat all comers. (So much for competitiveness and a level playing field!) We should, therefore, be very certain that services diverted from hospitals be associated with some overwhelming public good because there will surely be public harm as hospitals restrict services to the poor and vulnerable in any effort to remain afloat while enduring further reductions in their paying customer mix. Florida is ***one state that has used CON to ensure access for indigent patients and presumably blunt this threat.*** END OF QUOTE

In a March 2004 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) found that the hospital payment rate exceeds the ASC payment rate for 87 percent of the surgical procedures that Medicare pays for in an ASC. A recent study showed that Medicare procedures on average cost $320 less in an ASC than in a hospital.[3]

In addition, Medicare beneficiaries generally pay lower co-payments at ASCs when compared to hospitals. Private payers also are driving ASC growth in many areas because they recognize the efficiencies and savings inherent in ASC settings. The Office of Inspector General noted that the federal Department of Health and Human Services has been "promoting greater utilization of ASCs because of the substantial cost savings to Federal health care programs when procedures are performed in ASCs."[4]

Yet, despite the clear benefits of ASCs in terms of quality and costs, some would advocate to this committee modifying CON regulations in a manner which could cripple further development of

[2] Outcomes Monitoring Data, FASA, First Quarter, 2005
[3] Moran Company Study, 2005
[4] Federal Register, Volume 64, #223, Page *63537,* Dated November 19, 1999

such an important industry. I believe that such regulatory restrictions on the development of ASCs are counterproductive to prudent health planning because they tend to stifle the innovations in technology and service delivery that have made ASCs so successful. Moreover, there is no evidence to suggest that the creation of ASCs results in the performance of excessive or medically unnecessary surgery services.

Access has also been brought up as an issue. I would suggest that in considering this issue you look not only at the surgical capacity needed today, but also explore what will be needed tomorrow. Increasingly, public policy makers are becoming concerned about our ability to meet tomorrow's surgical needs. It is predicted that the demand for surgery will grow significantly over the next few decades. A recent study estimates that there will be a 15 percent increase in the number of ophthalmology procedures performed by 2010 and a 47 percent increase by 2020.~ Other specialties are also expected to experience significant increases in demand. As a result we will need more operating rooms and more surgeons.

ASCs can contribute to our expanding surgical needs by providing additional operating rooms. Many of these procedures are ideal for the ASC setting. By performing these in ASCs, hospital operating rooms will be available for inpatient surgery where demand will also increase. For example, by 2020 it is predicted that there will be a 41 percent increase in the number of cardiothoracic procedures.[6] ASCs make it possible for surgeons to operate more efficiently and thus fewer operating rooms and fewer surgeons are needed to meet the demand. Steps taken today will determine how well we will meet the surgical needs of tomorrow. The community will be better served by acting now to expand surgical capabilities and efficiency rather than waiting until there is a crisis.

It is suggested in previous testimony that a rationale for limiting development of ASCs is the misconception that ASCs pull paying patients away from the hospital leaving it with non-paying or low paying patients. Several factors suggest that this does not occur. Looking at hospital data, one finds that between 1994 and 2001 – a major period of ASC growth – hospital costs for uncompensated care as a percent of revenue declined slightly.[7] If ASCs resulted in a major shift of paying patients away from hospitals thereby exacerbating the uncompensated care problem significantly, you would expect uncompensated care as a percent of revenue to increase, not decline.

A national organization of ASCs surveyed surgery centers and found that Medicaid constitutes at least *5* percent of gross revenues for 27.9 percent of ASCs. For 16.1 percent of ASCs, Medicare makes up more than 50 percent of gross revenues.[8] Unfortunately, the Medicaid program in Michigan does not give ASCs the opportunity to provide care to these patients. Medicaid system inadequacies do not allow physicians to treat Medicaid patients in ASCs, despite their willingness to do so. A recent study shows the median percent of Medicare business for ASCs is 28 percent. This is despite many policies that limit the ASC's ability to treat these patients. In most cases, Medicare and other third party payors pay those facilities less than hospitals for

[5] The Aging Population and its Impact on the Surgery Workforce, Dr. David Etzioni et,al., Annals of Surgery, Vol 238 #2, August, 2003

6 The Aging Population and its Impact on the Surgery Workforce, Dr. David Etzioni et,al., Annals of Surgery, Vol 238 #2, August, 2003

[7] MedPac Report to Congress, March 2003

8 FASA 2004 Survey

performing the exact same services. Moreover, due largely to Medicare restrictions on the scope of services that can be furnished in ASCs, hospitals continue to be the dominant setting for ambulatory surgeries. According to MedPAC's 2004 Report to Congress, hospitals accounted for more than half *(53.1* percent) of the most common ambulatory surgical procedures in 2001, compared[to 22.8 percent for ASCs and 24.1 percent for physician offices.

In fact, ASCs have proven to be very good for the economy, the state, businesses, and citizens without escalating costs.

In addition, ASCs produce added revenues in taxes. I looked up the annual financial report from a very large health care system in the state of Michigan. Their community benefit was equal to approximately 3.89% of their annual net revenue. I then figured out a large surgical center's investor contribution in terms of taxes, which ended up being 7.53% of net revenue. The 7.53% tax contribution to the community does NOT include the difference between the surgical center's cost of care for Medicare patients and the reimbursement. However, the large health care system does include this in their figures. I have heard many people say ASCs should do their fair share. I say ASCs are doing more than they are getting credit for! In fact, almost twice as much! The investors who put up the funds for the ASC are taking the risk, not the taxpayers and community. There are surgical centers that do not survive and those owners have lost money. There are also surgical centers that survive and thrive and do so at a reasonable cost to their customers and at a substantial benefit to their community.

Thus, if the playing field for outpatient surgery is unlevel in any way, it would appear that hospitals are the ones who have a distinct competitive advantage resulting from their ability to obtain higher payments for a broader range of procedures.

We have many fine hospitals that are critical to the residents of Michigan and I want them to succeed. The same physicians who practice in many of our ambulatory surgical centers also practice in the hospitals and care for many indigent patients. We have many fine physicians in Michigan that want our hospitals to succeed. Hospitals take care of many critically ill individuals and are necessarily tax exempt in order to alleviate the burden of indigent patient care costs.

In summary, ASCs offer access choices and physician efficiencies that hospitals have sometimes not been able to deliver. It is noteworthy that access to specialists is improved when the efficiency is increased. Physicians enjoy a very efficient environment in ambulatory surgical centers that is less likely to be interrupted by emergencies. On a quality level, Ambulatory Surgical Centers that participate with Medicare go through quality scrutiny and comply with accreditation standards in the same fashion as their hospital neighbors. Cost is generally lower at surgical centers, efficiency higher, and the capital risk is personal capital risk and not community risk.

I agree with what the SS SAC is trying to do in terms of some tightening or clarifying of the CON rules. I was able to witness the hours of intelligent and thoughtful work done by both workgroups on behalf of the SSSAC and the citizens of Michigan and I support the workgroups' recommendations. I also can give nothing but praise to the hard work of Cheryl Miller in leading this group. However, I believe the SSSAC is completely ignoring the need for compliance beyond "soft compliance" and in effect condoning those organizations that ignore patient needs and demands. You are being obstructionists to new and potentially innovative competition by

allowing the current organizations to submit data three months after the close of the calendar year, and even then some organizations ignore the request. This will always allow all current facilities ito know the market potential well in advance of any new entrants. Existing facilities may even undergo construction in order to prevent competitors from establishing a need for facilities or equipment. I would encourage this group to consider data requirements on a monthly basis. I also encourage the group to continue to consider the best interests of the citizens of Michigan in terms of quality, cost, and access and not overlook the attributes of ambulatory surgical centers, even those not owned by hospitals, as a valuable addition to our citizens' health care choices. Hopefully at the next SSSAC in three years instead of considering what should not be done in the ASC or hospital because it can be done at the physician's office, we will be considering the list of procedures inappropriate to do in a hospital outpatient setting because they can be done in the ambulatory care center.

Thank you for your consideration of my comments.

6

ATTACHMENT D

Descriptives

2004 Hospital & Freestanding
Sept. 20, '05
Draft

Descriptive Statistics

	N	Minimum	Maximum	Sum
Trauma level certification	140	1	2	263
Burn care certification	140	1	2	276
Number of operating rooms on sterile corr. for IP/OP	140	1	47	939
Number of surgical cases in OR's on sterile corr. for IP/OP	140	98	34450	836356
Number of hours of use of OR's on sterile corr. for IP/OP	135	69.00	904852.00	2299414.2
Number of Ded. endo/cysto sterile operating rooms for IP/OP	117	0	6	80
Surgical cases in Ded. endo/cysto operating room for IP/OP	88	0	7865	76694
Hours of use of ded. endo/cysto operating rooms for IP/OP	84	.00	5065.00	54474.78
Valid N (listwise)	83			

Descriptives

Freestanding

Descriptive Statistics

	N	Minimum	Maximum	Sum
OR on Sterile Corridor	68	0	6	193
Cases in OR	68	0	8265	201023
Hours in OR	64	.0	9074.3	139243.5
Dedicated Endo/Cysto OR	54	0	10	20
Cases in Ded. Endo/Cysto OR	24	0	15454	35652
Hours in Ded. Endo/Cysto OR	24	.0	5400.0	12533.1
Valid N (listwise)	20			

OR's on Sterile Corr. 1,132
Ded. Endo/Cysts 100